APR 5 2005 K050505 (1 of 4)

Imprint Pharmaceuticals Ltd

Summary of Safety & Effectiveness for 510k Application

1 **Imprint Contact Person:**
Mervyn Little
Device Development Director
Imprint Pharmaceuticals Ltd.
53 Langton Road
East Molesey
Surrey KT8 2HX
Phone +44 208 224 9958
E-mail: Mervyn.Little@imprintpharma.com

2 **Device Name:** DepotOne™

3 **Common Name:** Hypodermic Needle

4 **Classification Name:** Hypodermic Single Lumen Needle (880.5570)

5 **Predicate Device:** K-Pack II Needle. Ref K984576

6 **Product Description:** Single use Hypodermic Needle.

7 **Intended Use:** DepotOne is a sterile single use hypodermic single lumen needle intended for the injection and removal of fluids from below the surface of the skin in humans.

8 **Description:** The DepotOne needles comprise of a length of Hypodermic grade stainless steel tube connected to a female connector (hub) that is designed to mate with a male connector of a piston syringe or an intravascular administration set. The other end of the tube is sharpened with a lancet tip in accordance with ISO7864: 1993. The sharpened section of tube is of a reduced diameter. The fluid is injected or removed through a side aperture adjacent to the sharpened tip.

9 **Substantial Equivalence:** The DepotOne™ needles in this 510k submission are substantially equivalent in intended use, principles of operation and materials to the cleared K-Pack Hypodermic Single Lumen Needle that is the subject of K984576. The differences between the devices cited in this section do not raise any new safety issues or new issues relating to effectiveness.

K945945 (p.2 of 4)

Design & Materials:

DepotOne and K-Pack II needles are manufactured from stainless steel hypodermic grade tube.
The tip of DepotOne™ is reduced in diameter. An opening is ground into the side of the tube close to the sharpened tip to facilitate the delivery or removal of the fluids. The tip diameter of the K Pack II needle is not reduced, the opening is in the tip. Both needles are sharpened at the tip in accordance with ISO7864.
The proximal end of both needles is securely attached to a 6% Luer connector by means of an epoxy adhesive. The Luer connector is a locking fitting and is in accordance with ISO 594-2 (the K-Pack needle Luer connector does not completely meet the requirements of ISO 594-2). The connector is colour coded in accordance with ISO 6009.The DepotOne connector is manufactured from polycarbonate. The material differs from the material used in the predicate devices and was selected for its superior bond strength when glued. The difference in the materials does not have any impact on the sterilisation. The polycarbonate used in the manufacture of the hub is approved for EO and gamma sterilisation by the manufacturer.
Both needles are supplied fitted with a rigid moulded polypropylene needle tip protector (shield). The colour of this moulding is clear.
Both needles are sterilised using ethylene oxide (ETO).
The difference between DepotOne and the predicate device do not raise any significant issues of safety and effectiveness and do not affect the substantial equivalence.

Proposed Product:

Product Code	Needle Gauge	Needle Length	Needle Bevel
D118021	23/18G XTW	3/8"	Standard Lancet
D118022	23/18G XTW	½"	Standard Lancet
D118023	23/18G XTW	¾"	Standard Lancet
D118024	23/18G XTW	1"	Standard Lancet
D118025	23/18G XTW	1 ¼"	Standard Lancet
D118026	23/18G XTW	1 ½"	Standard Lancet

Product Code	Needle Gauge	Needle Length	Needle Bevel
D118041	27/21G XTW	3/8"	Standard Lancet
D118042	27/21G XTW	½"	Standard Lancet
D118043	27/21G XTW	¾"	Standard Lancet
D118044	27/21G XTW	1"	Standard Lancet
D118045	27/21G XTW	1 ¼"	Standard Lancet
D118046	27/21G XTW	1 ½"	Standard Lancet

K050505 (2.3.04)

Materials:

Component	Predicate K984576	Proposed DepotOne™
Cannulae	Stainless Steel	Stainless Steel
Hub (6% Locking Luer)	Polypropylene	Polycarbonate
Needle Lubricant	Silicone	Silicone
Adhesive	Epoxy	Epoxy
Sterilisation Method	ETO	ETO
Needle Shield	Polypropylene	Polypropylene

EN ISO 7864:1993 Sterile Hypodermic Needles for Single Use.

DepotOne™ conforms to the requirements of ISO 7864:1993 Sterile Hypodermic Needles for Single Use.

Tests

DepotOne™ needles have passed the following tests:

Bend tests to EN ISO 9626:1995 Stainless Steel Tubing for the Manufacture of Medical Devices. (see note)
Breakage tests to EN ISO 9626:1995 Stainless Steel Tubing for the Manufacture of Medical Devices.
Needle/Hub Bond tests to EN ISO 7864:1993 Sterile Hypodermic Needles for Single Use.
Patency of Lumen tests to EN ISO 7864:1993 Sterile Hypodermic Needles for Single Use.
Extractables tests to EN ISO 7864:1993
Acidity and alkalinity tests to EN ISO7864: 1993

Additional tests: Fluid Flow Tests, Breakage tests for completed needles, Bend tests for complete needles includes the swaged tip, Penetration force tests.

None of the tests raised any issues relating to safety or effectiveness.

Note:

DepotOne™ XTW needles have passed all the above tests. However it should be noted that ISO9626 (Stainless Steel Tubing for the Manufacture of Medical Devices) does not specify a maximum deflection for 1.2mm (18G) XTW tube or 0.8mm (21G) XTW tube (no data is presented in the standard).
The nearest data available is for 19G XTW and 22G XTW tube. The 1.2mm XTW tube passes the requirements for 1.1mm (19G) XTW tube and the 0.8mm XTW tube passes the requirements for 0.7mm (22G) XTW tube.

Sterilisation

DepotOne™ needles have been subjected to and passed the following tests:

DepotOne needles are EO sterilised by a validated sterilisation method in accordance with the requirements of EN550. The sterilisation of DepotOne™ has been certified to comply with the requirements of EN556 and validated by an independent laboratory to a Sterility Assurance Level (SAL) of 10^{-6}.

Bioburden test.

DepotOne needles have been tested for freedom of Pyrogens by means of LAL (limulus amebocyte lysate) test conducted by an independent laboratory in accordance with European Pharmacopoela.

A LAL test is performed on samples from every production batch/lot.

DepotOne needles have been tested for residual gas contents test in accordance with EN ISO10993-7. Limiting value 20mg ethylene oxide/24hrs.

Conclusion

The DepotOne™ needles submitted in this 510k file are substantially equivalent in intended use, design principles, operation, and materials to the cleared K-Pack Single Lumen Needle that is subject to K984576.

The differences between the devices cited in this section do not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 5 2005

Imprint Pharmaceuticals Limited
C/O Mr. Tamas Borsai
Responsible Third Party Official
TUV Rheinland of North America, Incorporated
12 Commerce Road
Newton, Connecticut 06470

Re: K050505
Trade/Device Name: DepotOne™
Regulation Number: 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: March 17, 2005
Received: March 21, 2005

Dear Mr. Borsai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Intended Use

510(k) Number	K050505
Device Name:	DepotOne™
Intended Use	DepotOne is a sterile hypodermic single lumen needle intended for the injection and removal of fluids from below the surface of the skin in humans. The needle is intended to interface with the male luer connector of a syringe or intravascular administration set. The needle is intended for single use only.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

...vision Sign-Off)
...vision of Anesthesiology, General Hospital,
...fection Control, Dental Devices

...10(k) Number: K050505